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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/737,176 | 12/13/2000 | Josef V. Koblish | 15916-279 | 8413 |

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 05/09/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/737,176 | KOBELISH ET AL. |
| | Examiner | Art Unit |
| | Michael Peffley | 3739 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-28,33,36,37,39 and 41-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 12-14,26-28,33,36 and 37 is/are allowed.

6) Claim(s) 1,3-11,15-25,39 and 41-48 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22. 6) Other:

Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 17, 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 39, 41-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al ('484).

Concerning claim 39-43 and 45, the Gough et al device comprises a surgical probe (16) having a relatively short shaft with an inflatable, energy transmitting portion (23) associated with the distal end, and a cooling fluid source connected to the inflatable energy transmitting element and adapted to maintain pressure at a predetermined level (controlled by the fluid flow rate). While Gough et al do not expressly state that the fluid is a "cooling fluid", the examiner maintains that it inherently serves that function since it is a flowing fluid provided at a lower temperature (i.e. ambient temperature) than the heat-generating electrode. The fluid is inherently continuously infused and ventilated since there are micropores for delivery of the fluid from the balloon.

Claims 39, 41-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Qian ('028).

Qian provides a device with a relatively short shaft (10) with an inflatable, energy transmitting element (18) located at the distal portion of the shaft. A fluid is provided to the inflatable member under sufficient pressure to inflate the balloon. Also, the fluid would have inherent cooling properties since it is lower in temperature than the heated energy delivery element, and further since the fluid is continuously infused and vents through micropores in the balloon (see Abstract and col. 2, lines 13-19). The shaft is deemed to be relatively short as it is used in the esophagus (col. 2, lines 8-12) which does not require a lengthy or flexible tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-8, 11, 15-20, 24, 25 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) in view of the teaching of Deslauriers et al ('678)

As addressed previously with respect to the 35 USC 102(b) rejection, Qian discloses a device which comprises a relatively short shaft (10) with an inflatable, energy transmitting lesion formation element (18) associated with the distal portion of the shaft. Qian fails to specifically teach that the shaft is relatively stiff and/or malleable. However, Qian does teach that the device is an esophageal device.

Deslauriers et al disclose an analogous device which comprises a relatively short, relatively stiff shaft having a balloon member at the distal end for esophageal applications. In particular, Deslauriers et al teach that it is desirable to provide the relatively short shaft with a malleable configuration support (col. 9, lines 1-7) to aid in the insertion of the device into the esophagus.

Concerning claims 6-8 and 18-20, the entire surface of the Qian device is deemed to be an energy transmission region and includes a distally facing region (i.e. at the distal end of the balloon) and a proximally facing region and surrounds a non-conductive region (shaft 10).

To have provided the Qian device with a malleable shaft to facilitate its insertion into the esophageal space would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Deslauriers et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teaching of Lundquist (923).

The combination of Qian with the Deslauriers et al teaching has been addressed. There is no specific teaching in Deslauriers et al of providing varying degrees of malleability along the length of the device.

Lundquist provides a general teaching that it is known to provide varying degrees of malleability along the length of a shapeable medical device. More particularly,

Lundquist teaches that it is desirable to provide the distal portion of a device with more flexibility than the proximal portion (col. 24, lines 1-30).

To have provided the Qian device, as modified by the teaching of Deslauriers et al, with a more flexible distal portion to facilitate locating the distal (i.e. active portion) of the device in tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Lundquist.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teaching of Swanson et al ('513).

The combination of Qian and Deslauriers has been addressed. Qian fails to disclose discrete energy transmitting and non-conductive regions on the balloon. Rather, the entire balloon serves as an energy transmitting member.

Swanson et al disclose an analogous energy transmitting balloon device, and specifically teach that the balloon may be provided with discrete energy transmitting and non-conductive regions on the balloon. The regions are dispersed along the balloon and may include annular portions facing distally and proximally (Figures 11 and 12). The conductive and non-conductive regions are visually distinctive and would be different colors due to the difference in materials.

To have provided the Qian device, as modified by the teaching of Deslauriers et al, with a plurality of conductive and non-conductive regions along the length of the

balloon to provide a distinct energy emitting characteristic would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Swanson et al.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qian ('028) and Deslauriers et al ('678) as applied to claim 3 above, and further in view of the teachings of Edwards ('241) and Abele et al ('311).

Qian discloses a means to provide a pressurized fluid to the balloon member such that fluid is perfused through micropores in the balloon. However, Qian fails to teach the particular pump and pressure control system, including a pressure sensor, for controlling the flow of fluid.

Edwards provides a substantially identical device to that of Qian. It includes an energy emitting balloon member, and means to provide pressurized fluid to the balloon such that the fluid is perfused through micropores in the balloon. Edwards specifically states that the fluid source may include a pump/pressure flow control device as is known in the art (col. 9, lines 1-15) and that the flow rate and pressure may be controlled (col. 10, lines 25-30). While the examiner holds that it is inherent that there is a means to monitor fluid pressure in order to control the pressure, there is no explicit or a pressure sensor used with the Edwards device. Abele et al disclose a balloon device with a fluid pump source, and specifically teach of the known use of a pressure sensor (9) located on the device for controlling the operation of a pump to provide a desired fluid flow.

To have provided the Qian device with a fluid pressure and flow control system, including a pressure sensor, to provide a desired fluid flow through the balloon would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Abele et al.

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Gough et al ('484) or Qian ('028) in view of the teachings of Edwards ('241) and Abele et al ('311).

As addressed in the 35 USC 102 rejections, both Gough et al and Qian disclose systems which include porous balloons which receive and perfuse a fluid (i.e. electrolytic solution). While Gough et al indicate that fluid flow/pressure may be controlled (col. 10, lines 1-7), neither reference shows the specific components to achieve the monitoring and control of a fluid within the balloon device.

Edwards provides a substantially identical device to that of Qian. It includes an energy emitting balloon member, and means to provide pressurized fluid to the balloon such that the fluid is perfused through micropores in the balloon. Edwards specifically states that the fluid source may include a pump/pressure flow control device as is known in the art (col. 9, lines 1-15) and that the flow rate and pressure may be controlled (col. 10, lines 25-30). While the examiner holds that it is inherent that there is a means to monitor fluid pressure in order to control the pressure, there is no explicit or a pressure sensor used with the Edwards device. Abele et al disclose a balloon device with a fluid pump source, and specifically teach of the known use of a pressure sensor

(9) located on the device for controlling the operation of a pump to provide a desired fluid flow.

To have provided either the Gough et al or the Qian device with a fluid pressure and flow control system, including a pressure sensor, to provide a desired fluid flow through the balloon would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Abele et al.

Allowable Subject Matter

Claims 12-14, 26-28, 33, 36 and 37 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are not persuasive.

With regard to the Qian patent, applicant contends that the Qian patent is for thrombosis and therefore does not meet the limitation of an "energy transmitting lesion formation element". While the examiner agrees that the intended use of the Qian patent is for creating thrombosis, the examiner disagrees that it does not meet the limitation of an "energy transmitting lesion formation element". There is not structurally different from the instant claimed invention and the Qian device other than the intended use limitation of a "lesion formation element". Qian provides an RF electrode which is inherently capable of acting in such a manner. The difference between creating a lesion and creating a thrombosis is a matter of energy delivery and time. That is, were the Qian device to be energized long enough, a lesion would certainly be treated (much like an iron is not intended to burn clothing but would certainly do so if left sitting on clothing

long enough). Applicant's claims do not recite a particular energy source or other connection to distinguish the particular level and/or amount of energy delivered through the device. The examiner maintains that the Qian device is inherently capable of creating a lesion in tissue and meets the structural limitations of the rejected claims.

Regarding the recitation that the device "continuously infuses fluid to and ventilates fluid from the inflatable, energy transmitting lesion formation element", the examiner again maintains that the prior art clearly meets this limitation. While the Qian patent states that the fluid is used to "inflate" and "fill" the balloon as asserted by the applicant, it is clear that the fluid must be continuously provided to keep the balloon in the inflated or full state since there are micropores located on the balloon which provide the fluid to tissue (see Abstract; col. 2, lines 40-50; col. 2, lines 8-18). If fluid is slowly flowing from the balloon, there must be more fluid flowing in (i.e. continuously infused) to maintain the balloon in its inflated, treatment condition. The fluid flowing through the pores is thereby ventilated from the balloon. There is nothing in the claims which provide a specific structural mechanism for infusing and ventilating the fluid to distinguish over the Qian reference.

Similarly, Gough et al provide a porous balloon member which continuously infuses fluid to the balloon to replace the fluid which is ventilated from the balloon to tissue. Again, the claims do not disclose a particular flow rate which prevents the interpretation of the fluid flowing to and from the balloon as infusion and ventilation of the balloon. Nor is there any specific structure (i.e. "fluid is ventilated from the balloon through the probe") to distinguish over the Gough et al reference.

Art Unit: 3739

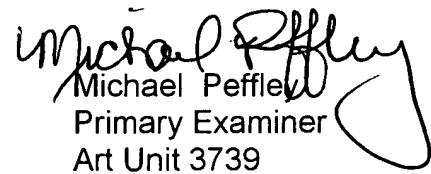
The examiner maintains that the rejections as set forth are tenable and are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
May 7, 2003